SARTORIUS

Product Datasheet

Octet® GlyM Kit

For High-Throughput Mannose Screening of Crude and Purified mAb and Non-mAb Protein Samples

Key Features

- Designed to analyze both crude and purified samples: no purification or digestion required
- Relative mannose content screening and ranking of samples into groups - high, medium or low
- High-throughput analysis of 96 samples, in parallel, in less than 1 hour

Overview

Glycosylation, an important post-translational modification, is a key critical quality attribute (CQA) that influences product safety and efficacy and should be monitored when developing new biological drugs. Among various glycan structures, mannose is especially important as it affects a protein's plasma clearance and reduces its *in vivo* half-life, negatively impacting drug efficacy. While process conditions, media and feed formulations are critical factors in the optimization of protein mannosylation, optimal cell line selection can be a limiting step; early screening for mannose content can facilitate the selection of clones that produce

proteins with favorable glycan profiles during cell line development (CLD).

The Octet® GlyM Kit enables high-throughput mannose content screening in crude cell culture samples during early clone selection stages in the CLD process. When combined with titer analysis, it expedites the selection of the top performing cell lines producing proteins with the most favorable glycan (mannose) profile (Figure 1).

Assay Workflow

The GlyM Kit utilizes mannose specific lectin which is immobilized onto the biosensor surface (Figure 2). This surface binds to mannose structures in the sample. The secondary amplification steps increase the binding signal from protein of interest (POI) and negates the minimal signal from host cell proteins (HCPs). This increases assay sensitivity, facilitating the analysis of crude cell culture samples without the need for purification or enzymatic digestion. This essentially eliminates the need for any sample preparation beyond a dilution step, simplifying the mannose screening workflow for users. Additionally, the GlyM Kit reduces time to results and increases sample analysis throughput. As a result, 96 clones can be screened in under 1 hour on the Octet® RH96 system. The GlyM Kit comes with the biosensors and reagents required to screen mannose content in up to 96 samples and is compatible with Octet® systems with at least 4 channels.

Relative Mannose Content Screening

The GlyM Kit enables the screening and ranking of crude samples based on the relative mannose content in the POI. The kit provides ranking results for samples with mannose content that differs by 4% or more (Figure 3, see samples with 3% vs. 8% and 10% vs. 14% Mannose content). Users can assign all screened clone samples into groups depending on the mannose content (*e.g.*, high, medium or low) and focus further development effort on the desired group of clones only.

Data Analysis

Octet® Analysis Studio software combines titer data with mannose content data for more in-depth analysis that facilitates selection of the best clones.

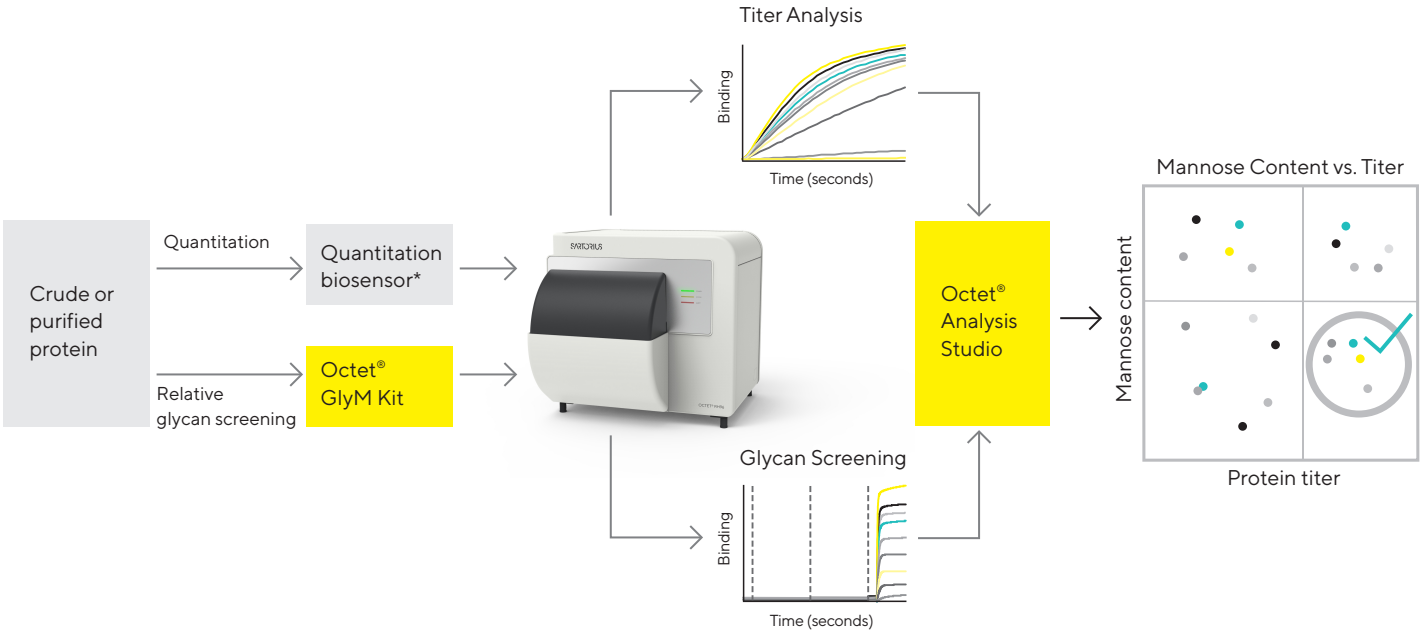

Figure 1: Typical CQA analysis workflow on the Octet® platform. Titer is measured using a ProA, HIS1K, ProG or other quantitation biosensor* and relative screening of mannose content is performed using the Octet® GlyM Kit. Octet® Analysis Studio software can then combine both data files to view sample representation with CQAs in one file and create reports for export.
**Not included with GlyM Kit.*

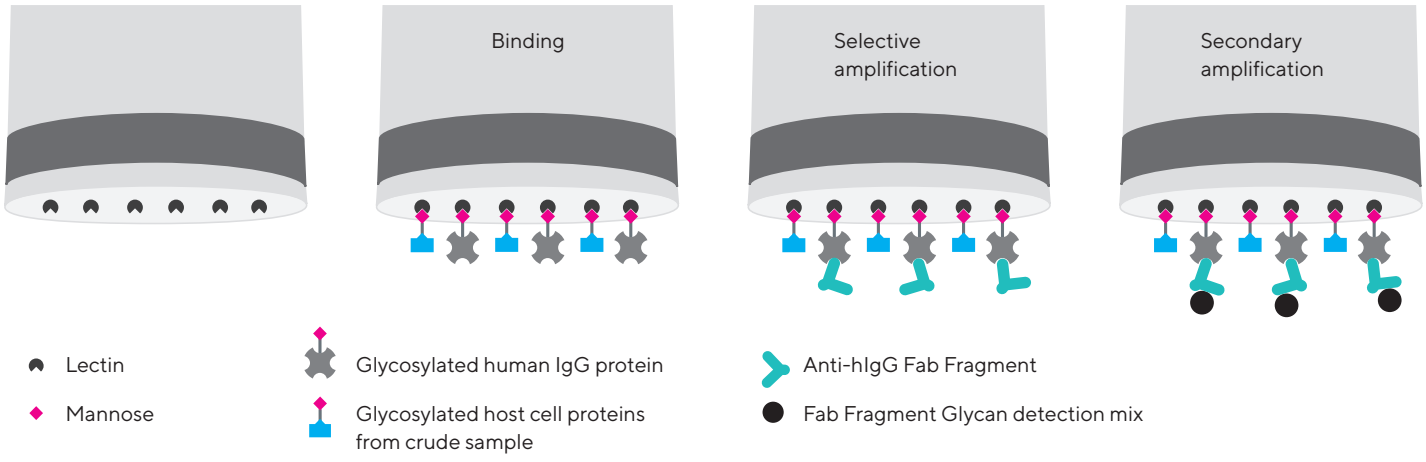

Figure 2: Example Octet® GlyM Kit assay workflow for human IgG. Selective amplification of signal from the protein of interest and not from HCP.†

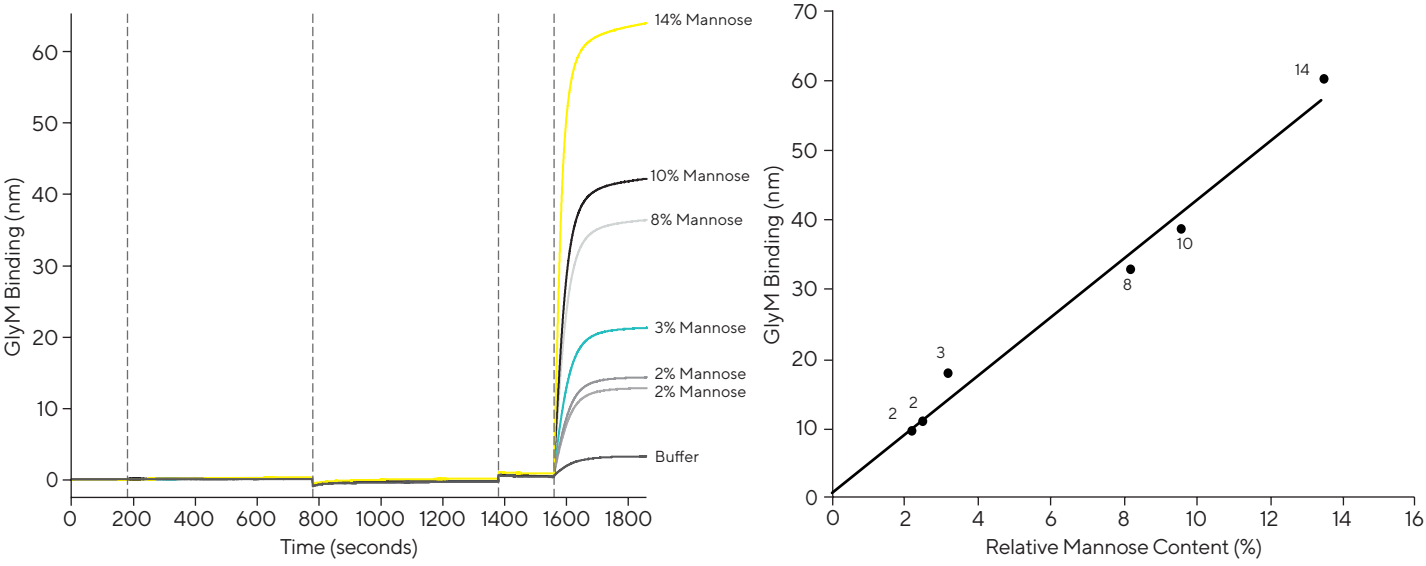

Figure 3: Example data illustrating mannose screening of hIgG samples using GlyM Kit (left). GlyM binding also correlates with the % mannose content determined by HPLC in the same samples (right).

Quick Facts

Assay type	1-step assay for purified non-mAB samples[§]
	3-step assay for crude/purified mAb sample with mannose content >1%
Assay specificity	High mannose, core mannose
Sample ranking	Assign samples into groups with high, medium, or low mannose content
Mannose content resolution	4% or more*

[§]This kit was tested using non-mAb samples with 75% mannose content.
*See Figure 3 (samples with 3% vs. 8% and 10% vs. 14% Mannose content).

Ordering Information

Part No.	Name	Description
18-5139	Octet® GlyM Kit**	Includes 1 Octet® GlyM Biosensor Tray (96 biosensors) and 1 Octet® GlyM Kit Reagent box containing: ▪ Octet® Glycan Buffer A ▪ Octet® Glycan Sample Prep Buffer ▪ Octet® Anti-hIgG Detection Fab ▪ Octet® Anti-hIgG Detection Fab Buffer ▪ Octet® Glycan Detection Substrate ▪ Octet® Glycan Detection Buffer Octet® Glycan Wash Buffer

** Please refer to the Octet® GlyM Kit Technical Note for other assay workflows and additional materials required.

† Requires Octet® BLI Discovery and Analysis Studio software version 12.2 or higher.

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